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(71) Applicants and
(72) Inventors: **SPYROPOULOS, Panayiotis, Spyros** [ZA/ZA]; 701 Hillside Village, 9th Street, 2193 Killarney (ZA). **SPYROPOULOS, Sophia, Maria** [ZA/ZA]; 701 Hillside Village, 9th Street, 2193 Killarney (ZA).

(74) Agents: **GILSON, David, Grant** et al.; Spoor and Fisher, PO Box 41312, 2024 Craighall (ZA).

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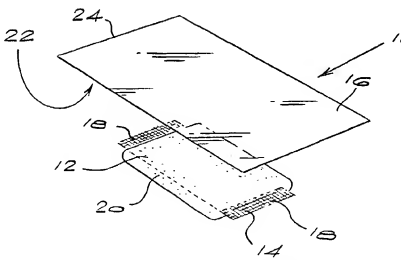
(54) **Title:** COMPOUND HYDROGEL WOUND DRESSING



(57) **Abstract:** The compound hydrogel wound dressing of the invention consists of an absorbent hydrogel layer, a mesh or scrim embedded in the hydrogel layer and an oxygen- and vapour-permeable outer or backing layer arranged to overlie the mesh reinforced hydrogel layer in use. The mesh includes winglets which extend beyond the peripheral boundary of the hydrogel layer. The undersurface of the outer layer is coated, either adjacent the periphery of the outer layer or over the entire surface, with a medical-grade, hypoallergenic pressure-sensitive adhesive. The arrangement is such that when the mesh reinforced hydrogel layer is applied over a wound the winglets of the mesh adhere to the coated undersurface of the backing layer. When the wound dressing is to be removed, the backing layer is peeled away from the patient's skin, drawing the mesh and hydrogel layer away from the wound.

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COMPOUND HYDROGEL WOUND DRESSING

BACKGROUND OF THE INVENTION

THIS invention relates to a compound hydrogel wound dressing.

Wound dressings, although provided in a number of different forms, are generally designed for certain desired results. For instance, the wound dressings are typically arranged to provide a barrier against infection, in particular bacterial infection, and to prevent accumulation or pooling of wound exudate. They are also preferably arranged to facilitate or promote wound healing.

Most wound dressings are therefore provided in the form of a hydrogel or similar substance for absorbing wound exudate. In some instances, the hydrogel is applied to the wound and is covered by an adhesive backing to keep the hydrogel in place. The problem with this type of arrangement is that when the hydrogel layer is to be removed, it is generally necessary for the medical practitioner to don surgical gloves and manipulate the gel layer from the wound. Due to the physical nature of the hydrogel, the removal is not always a simple task and this form of wound invasion is clearly not ideal.

An alternative form of wound dressing incorporates an adhesive on the hydrogel for adhering it to the wound. In such a case, a separate adhesive backing layer is generally not required. However, the adhesive layer tends to inhibit the absorption of wound exudate and also becomes less effective over time due to pooling of exudate. Once again, in order to remove the gel layer, the practitioner is required to pry it away from the wound with the same disadvantages as mentioned previously.

SUMMARY OF THE INVENTION

According to the invention, a compound hydrogel wound dressing comprises:

an absorbent hydrogel layer arranged to contact a wound for absorbing wound exudate from the wound; and

a mesh layer, at least a portion of which is embedded in the hydrogel layer to provide an element of structural integrity to the hydrogel layer.

The mesh layer preferably extends beyond the periphery of the hydrogel layer so as to provide means for removing the hydrogel layer from the wound.

The hydrogel layer is preferably transparent so as to allow for visual inspection of the wound without removing the wound dressing.

The wound dressing preferably includes an oxygen- and/or vapour-permeable outer layer, preferably transparent.

The outer layer is preferably coated on one of its major surfaces, either adjacent its periphery or over its entire surface, with a medical-grade, hypoallergenic pressure-sensitive adhesive, the outer layer being sized to overlie the mesh-reinforced hydrogel layer and contact the patient's skin about the periphery of the wound to adhere the wound dressing to the patient's skin.

The portion of the mesh layer extending beyond the boundary of the hydrogel layer is preferably arranged to contact the adhesive on the outer layer, the arrangement being such that when the outer layer is peeled away from the patient's skin, the mesh reinforced hydrogel is simultaneously drawn away from the wound.

In one version of the invention, the wound dressing is in a rectangular, substantially planar sheet form.

In an alternative version of the invention, the wound dressing is shaped to be placed within a wound cavity. For instance, the wound dressing may be tubular or semi-tubular and may be tapered to be accommodated within various wound cavities.

In yet a further alternative embodiment, the wound dressing may be in the form of a garment or portion thereof to be worn over a substantial portion of a patient's body, particularly in the case of burn patients. The wound dressing in this embodiment may be in the form of a vest, bib, glove, sock or the like.

The wound dressing of the invention may include an access passage for accommodating, in particular, a drip inserted into a patient and covered by the wound dressing.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention will now be described in more detail, by way of example only, with reference to the accompanying drawings in which:

Figure 1 is an exploded perspective view of a first embodiment of a wound dressing of the invention;

Figure 2 is a plan view of the wound dressing of figure 1;

Figures 3a and 3b are cross-sectional views of the wound dressing of figure 1 in use;

Figure 4 is an exploded perspective view of a second embodiment of a wound dressing of the invention;

Figure 5 is a plan view of a third embodiment of a wound dressing of the invention;

Figure 6 is a cross-sectional view on the line 6-6 of Figure 5;

Figure 7 is a plan view of a fourth embodiment of a wound dressing of the invention; and

Figure 8 is a pictorial view of the wound dressing of Figure 7 in use.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring to figure 1 of the accompanying drawings, a first embodiment of a compound hydrogel wound dressing 10 of the invention is shown. It consists of an absorbent hydrogel layer 12, a mesh or scrim 14 embedded in the hydrogel layer 12 and an oxygen- and vapour- permeable outer or backing layer 16 arranged to overlie the mesh reinforced hydrogel layer 12 in use, as shown in figure 2.

The mesh 14 includes winglets 18 which extend beyond the peripheral boundary 20 of the hydrogel layer 12. The undersurface 22 of the outer layer 16 is coated, either adjacent the periphery 24 of the outer layer 16 or over the entire surface 22, with a medical-grade, hypoallergenic pressure-sensitive adhesive. The arrangement is such that when the mesh reinforced hydrogel layer 12 is applied over a wound 26, as shown in figure 3a, the winglets 18 of the mesh 14 adhere to the coated undersurface 22 of the backing layer 16. When the wound dressing 10 is to be removed, the backing layer 16 is peeled away from the patient's skin 28, drawing the

mesh 14 and hydrogel layer 12 away from the wound 26, as shown in figure 3b.

The wound dressing may include an additional cover (not shown), which is removed during dressing application, to provide additional structural integrity to facilitate application of the device to a patient's skin, for storage and for processing and conversion of the film during manufacture.

The hydrogel layer 12, which is preferably transparent in order to allow the wound to be observed without disturbing the wound microenvironment, may be any appropriate hydrogel that is skin and wound friendly (hypoallergenic) and provides controlled absorption of wound-exudate away from the wound.

The term "hydrogel" is a generic name for many types of products of this nature. The hydrogel suitable for the invention may be water-insoluble, water-soluble, organo-soluble or organo-insoluble. It may also be of a three dimensional, non-thixiotropic, thixiotropic, elastic, flexible or rigid, cross linked chemical structure.

The hydrogel layer must provide a barrier to contamination or recontamination from, for example, faecal matter, bacteria, viruses, dirt and any other medically undesirable contaminants. They are preferably also arranged to deslough or dehisce necrotic wound tissue.

Thus, hydrogels that find application in the medical field as skin protectants, as a general cover for injured or burned skin, as a wound cavity filler, for transdermal medication delivery and/or iontophoretic medication delivery, for various cosmetic applications, or for post-operative surgery, skin donor sites, intravenous cannulae exudative, necrotic, dehiscing, and other types of wounds, may be used.

The hydrogels may be chemically tailored to absorb controlled amounts of wound-exudate at a controlled rate of absorption or, for example, for the

prevention of peripheral skin maceration and diffuse same away from the wound. Furthermore, the hydrogels can be tailored to control, if clinically required and/or if clinically indicated, the wound moisture levels or to add moisture upon application to the wound. They may also be arranged to control and adjust wound pH levels (topical acidification, etc), salinity levels, active ingredient levels, bacteriostatic/bacteriocidal ratios and other designed parameters to suit the desired result prior to or during the application. They are therefore preferably arranged to control the hypoxic wound environment by controlling the pO_2 (partial pressure due to oxygen) gradient between the outside environment and the wound microenvironment.

As mentioned previously, the hydrogels are preferably transparent or optically clear to provide for visual inspection of a wound without removal of the wound dressing 10. In this regard, the hydrogel may be translucent, radio-opaque, radiolucent, ultra-violet ray translucent, or coloured depending on the clinical requirements of the application.

The hydrogels are preferably sterilised. They may be sterilised by ionising or non-ionising methods such as gamma irradiation, electron beam irradiation, plasma, steam, ethylene oxide, ultra-violet sterilisation rays or the like.

Where desired, a perfume or medicament may be added to the hydrogel to mask or suppress undesirable odours from an infected wound or to make the product more acceptable or appealing from an olfactory standpoint. The hydrogels may be made non-adhesive or adhesive depending on the clinical requirement.

The hydrogel is preferably arranged to expand in use to eliminate "dead spaces" in the wound.

The hydrogel layer is also capable of being heated, for instance in a microwave, prior to skin or wound-cavity application. Heating the dressing

to near body temperature prior to the hydrogel application reduces the time taken by the body to raise the hydrogel to body temperature. This results in quicker stabilisation of the wound and its healing environment. An appropriate hydrogel/wound temperature results in increased mitosis for the creation of granulation tissue.

Referring now to the mesh or scrim 14, it is preferably a fibrous, spun-bonded or spun-laced, porous-structured, scrim type material, which may be formed of natural or synthetic mesh fibres. It is preferably manufactured of a lightweight transparent or opaque material such as standard or modified (poly)esters, rayons, (poly)olefins, (poly)amides, (poly)urethanes, (poly)ethers, (poly)ethylene tetraphthalates, cottons, polyamides, or fycological derivatives such as sea weeds, for example.

This fibrous mesh structure is incorporated in the hydrogel matrix and can be placed in any appropriate location within the hydrogel matrix. It provides an element of structural integrity to facilitate application of the hydrogel to the patient's skin, for storage of the dressing, removal of the dressing after usage, for re-application or repositioning of the dressing, and for processing and converting the hydrogel, scrim and film during manufacture.

The scrim preferably extends beyond the boundary of the hydrogel so that a portion of the mesh is not covered with hydrogel. This mesh is affixed to the pressure-sensitive adhesive coated to the filmic layer and facilitates removal of the dressing after use. This allows for intact removal of the hydrogel for weighing purposes to assess mass and provide for pathological analysis of wound exudates without wound irrigation.

The mesh material may be arranged to release an active ingredient into the gel. To this end, the fibres may selectively be manufactured of a fycological derivative such as calcium alginates or sodium alginates, or constituents thereof including other wound-active ingredients.

The outer cover or backing layer 16 is typically a filmic layer disposed over the hydrogel reinforced layer 12. It is preferably oxygen-, gaseous- and vapour-permeable and is adapted for transparency, flexibility, non-reflectance, skin-tone colouring (if indicated), and coated with a medical-grade hypoallergenic pressure-sensitive adhesive. This layer should ideally be suited for prolonged skin contact and for the transpiration of excess moisture accumulated under, on top of, or within the hydrogel layer. It also provides a further barrier to the contaminants discussed above. It is also preferably elastic or stretchable to provide for patient activity, waterproof to facilitate bathing, and may include a peel tab for ease of dressing removal.

So-called "breathable films" suitable for use with the wound dressing of the invention are thin, artificially synthesized, filmic structures that allow for the transpiration of the bi-directional flow of gases such as oxygen and moisture vapour, for example, between the skin and the surrounding atmosphere. Breathable films are usually thin, varying from 0.1 to 1000 microns and having, by design, moisture transmission rates of between 100 and 10 000 grams of oxygen per square metre of surface area over a controlled period of time – usually 24 hours. An industry standard test method to validate moisture transmission rate (MVTR) through a porous membrane is described in Mocon method ASTM E-96 as "Procedure B". Variations of this test exist and the MVTR data needs to be compared to accepted "industry standard" test procedures at specified temperatures to allow for comparison.

The transparent films may be manufactured of standard or modified (poly)olefins, (poly)amides, (poly)esters, (poly)urethanes, (poly)ethers, or (poly)ethylene tetraphthalates, for example.

The additional layer of material or cover which is removed during dressing application is formed of an appropriate material such as polyester, polyethylene, polypropylene, or the like.

Referring now to figure 4 of the accompanying drawings, there is shown a second embodiment of a compound hydrogel wound dressing 40 of the invention. The would dressing 40 consists of a tapered, tubular hydrogel body 42 reinforced with a mesh layer 44 embedded therein. An outer layer or backing 46 is arranged to overlie the hydrogel body 42 when the latter is placed in a wound cavity (not shown). Although not shown in this embodiment, the mesh layer 44 may also be arranged to extend beyond the periphery 48 of the hydrogel body 42 in order to engage an adhesive coated on the underside 50 of the backing layer 46, in order to assist in removal of the body 42.

Although in this embodiment the hydrogel body 42 has a semi-tubular shape, it may be any appropriate three-dimensional shape to suit a particular wound cavity.

Referring now to figure 5 of the accompanying drawings, there is shown a third embodiment of a compound hydrogel wound dressing 60 of the invention. In this embodiment, the wound dressing 60 is in the form of a vest. As shown more clearly in figure 6, it includes a hydrogel layer 62, a mesh or scrim 64 embedded therein and a cover 66, as described above with reference to the first embodiment 10.

In this embodiment, the wound dressing 60 includes a pair of body engaging panels 68 extending away from a central portion 70, including a neck portion 72. The wound dressing 60 is arranged such that the neck portion 72 is able to pass over the head of a patient such that the panels 68 are able to engage the back and front portion of the torso of the patient.

As described with reference to the wound dressing 10, when the wound dressing 60 is to be removed, the backing layer 66 is peeled away from the patient's body drawing the mesh reinforced gel layer 62 with it.

Although a vest is described in this embodiment any appropriate "garment" is envisaged. Thus it could be in the form of a bib, a glove, a sock, or similar article.

The wound dressing 10 described above may be modified in order to provide an intravenous dressing cover. Thus, referring to figure 7 of the drawings, an intravenous dressing cover 80 includes a hydrogel layer 82, a mesh 84 embedded therein and an adhesive coated cover 86. It also includes a cut out portion 88 defining an access passage for accommodating an intravenous drip 90 or the like as shown in figure 8. In this embodiment, the hydrogel layer is arranged to draw blood away from the puncture site of the intravenous needle in a similar manner as described with reference to the wound dressing 10 above.

The various components of the wound dressings 40, 60 and 80 are as described with regard to the wound dressing 10, with obvious variations where appropriate.

The compound hydrogel wound dressing of the invention described above not only provides for the expediting of wound healing by creating an optimum wound healing microenvironment, it also facilitates the removal or replacement thereof with minimal trauma to the wound site.

CLAIMS

1. A compound hydrogel wound dressing comprising:

   an absorbent hydrogel layer arranged to contact a wound for absorbing wound exudate from the wound; and

   a mesh layer, at least a portion of which is embedded in the hydrogel layer to provide an element of structural integrity to the hydrogel layer.

2. A wound dressing according to claim 1, wherein the mesh layer extends beyond the periphery of the hydrogel layer so as to provide means for removing the hydrogel layer from the wound.

3. A wound dressing according to claim 1 or claim 2, wherein the hydrogel layer is transparent so as to allow for visual inspection of the wound without removing the wound dressing.

4. A wound dressing according to any one of the preceding claims further comprising an oxygen- and/or vapour-permeable outer layer.

5. A wound dressing according to claim 4, wherein the outer layer is transparent.

6. A wound dressing according to claim 5, wherein the outer layer is coated on one of its major surfaces, either adjacent its periphery or over its entire surface, with a medical-grade, hypoallergenic pressure-sensitive adhesive, the outer layer being sized to overlie the mesh-reinforced hydrogel layer and contact the patient's skin about the periphery of the wound to adhere the wound dressing to the patient's skin.

7. A wound dressing according to claim 6, wherein the portion of the mesh layer extending beyond the boundary of the hydrogel layer is arranged to contact the adhesive on the outer layer, the arrangement being such that when the outer layer is peeled away from the patient's skin, the mesh reinforced hydrogel is simultaneously drawn away from the wound.

8. A wound dressing according to any one of the preceding claims, wherein the wound dressing is in a rectangular, substantially planar sheet form.

9. A wound dressing according to any one of claims 1 to 7, wherein the wound dressing is shaped to be placed within a wound cavity.

10. A wound dressing according to claim 9, wherein the wound dressing is tubular or semi-tubular, and is optionally tapered to be accommodated within various wound cavities.

11. A wound dressing according to any one of claims 1 to 7, wherein the wound dressing is in the form of a garment or portion thereof to be worn over a portion of a patient's body.

12. A wound dressing according to claim 11, wherein the wound dressing is in the form of a vest, bib, glove, sock or the like.

13. A wound dressing according to any one of claims 1 to 7 further comprising an access passage for accommodating a drip inserted into a patient and covered by the wound dressing.

14. A compound hydrogel wound dressing substantially as herein described with reference to any one of the illustrated embodiments.

Fig 1

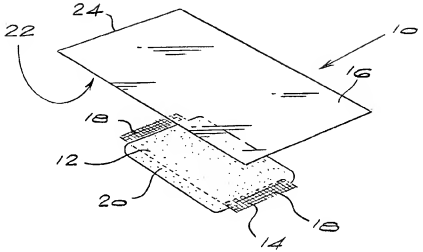
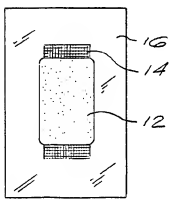


Fig 2



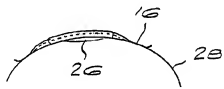


Fig 3a

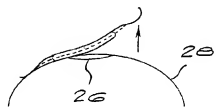


Fig 3b

FIG 4

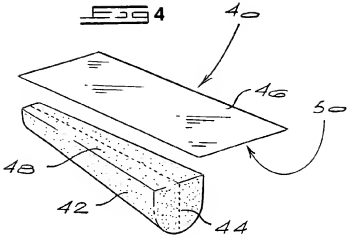


FIG 5

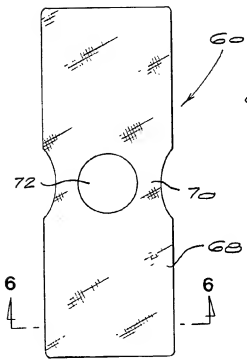
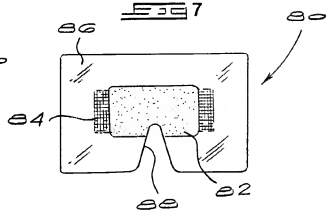


FIG 7



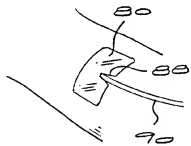


FIG 6

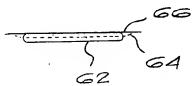


FIG 8